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COMMITTEE ON AGRICULTURE
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Congress of the United States
House of Representatives

April 6, 2017

The Honorable Tom Cole
Chairman
Subcommittee on Labor, Health, and Human Services, and Education
House Appropriations Committee
Washington, DC 20515

The Honorable Rosa DeLauro
Ranking Member
Subcommittee on Labor, Health, and Human Services, and Education
House Appropriations Committee
Washington, DC 20515

Dear Chairman Cole and Ranking Member DeLauro:

Lyme disease and related tick-borne illnesses are a serious and growing threat to public health. These diseases are poorly understood, rapidly spreading and can be debilitating. Lyme disease is the most common vector-borne disease and the second most commonly reported bacterial infectious disease in the United States, with 389,000 new cases reported in 2015 at an annual economic cost of more than $4.2 billion, according to CDC estimates. Cases of other tick-borne diseases, including Anaplasmosis, Babesiosis, Ehrlichiosis, Powassan virus, and Rocky Mountain spotted fever, are increasing and can complicate diagnosis and treatment for patients who are co-infected with multiple pathogens. Unreliable diagnostic tests, treatment regimens that fail up to 36 percent of the time, underreporting and inaccurate surveillance, inadequate programs for prevention, and insufficient federal funding for research have created a perfect storm of unmet medical need and patient suffering.

Because of CDC's endorsement of clinical practice guidelines that are based on outdated science and are non-compliant with current standards, many Lyme sufferers are undiagnosed or misdiagnosed, refused appropriate treatment, and denied insurance coverage. Hundreds of thousands of Lyme patients experience a greatly diminished quality of life, compounded by financial hardships from out-of-pocket costs and lost income. The burden on individuals as well as on the U.S. economy from lost productivity, medical expenses, and disability is enormous, the suffering is widespread, and much of this is preventable.

Despite the severity and extent of the epidemic, remarkably little research funding has been allocated. The National Institutes of Health (NIH) FY 2017 funding for Lyme disease is $25 million. This amount has remained relatively constant for the past decade–despite a rapid growth in reported cases and research showing that the Lyme bacterium can evade the immune system, resist standard antibiotic treatment, and persist.

In addition, a growing body of research shows that co-infections complicate diagnosis and treatment of Lyme disease and that many patients require long-term therapy to regain their health. A 2015 study by the Johns Hopkins Bloomberg School of Public Health found that the "prolonged impact of the tick-borne illness in some patients is greater and more widespread than previously understood." As a result, undiagnosed, misdiagnosed, untreated, or inadequately treated Lyme disease patients represent an enormous social and economic burden with life-long costs for unemployment, Medicaid,

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Medicare, disability, and welfare for people who can no longer work or manage everyday activities.

To help address these issues, this paper proposes directives for inclusion in the report language for CDC and NIH FY 2018 budget appropriations. The proposed directives can help improve health outcomes and reduce the burden of Lyme disease and related tick-borne illnesses on the U.S. economy. The reports requested from CDC and NIH will help Congress better understand the impact of the epidemic and the effectiveness of agency programs to improve surveillance, prevention, diagnosis, and treatment. This information will provide a foundation to help justify the funding needed to combat this growing threat to public health.

The following language is proposed for inclusion in the Committee's report for the fiscal year (FY) 2018 Labor, Health and Human Services, Education, and Related Agencies Appropriations Act.

Centers for Disease Control and Prevention

Vector-Borne Diseases.--Vector-borne diseases, such as Lyme disease, West Nile Virus, and Zika, have high human consequences and are a growing threat to public health. The impacts of these diseases as well as the effectiveness of programs for surveillance, prevention, and control need to be better gauged and understood. Therefore, the Committee directs CDC to include goals and performance indicators for each high priority vector-borne disease in its annual congressional justification. Specifically, for each disease, the Committee recommends that CDC quantify goals and include performance indicators in the following categories:

(1) Preventing new infections,
(2) Improving access to care,
(3) Improving health outcomes, and
(4) Reducing disease-related disparities and health inequities.

No later than September 30, 2018, the Committee directs CDC to submit a report to the Committee that:

(1) Compares funding for high priority vector-borne diseases to the burden of disease as defined by Disability Adjusted Life Years (DALYs), and
(2) Includes estimates for the burden of each high priority vector-borne disease on the U.S. economy, including direct medical costs, indirect medical costs, nonmedical costs, and productivity losses.

Tick-Borne Diseases.--The Committee believes that prevention and control of tick-borne diseases should be a high priority. Therefore, the Committee directs CDC to increase resources allocated to surveillance and prevention of Lyme disease and other high-consequence tick-borne diseases in endemic areas as well as areas not yet considered endemic. The Committee encourages CDC to work closely with states to advance the use of Integrated Pest Management (IPM) for prevention and control of tick-borne diseases. IPM is a science-based decision-making process that identifies and reduces risks from pests and pest management related strategies. IPM coordinates the use of pest biology, environmental information, and available technology to prevent unacceptable levels of pest damage by the most economical means while minimizing risk to people, property, resources, and the environment.

The Committee encourages CDC to issue Funding Opportunity Announcements under its Emerging Infections Program that give priority to programmatic activities for Lyme disease and other tickborne diseases in the areas of surveillance, control, and prevention. The Committee recommends that CDC give high priority to proposals aimed at reducing the population of ticks known to transmit pathogens with high human consequences and reducing their ability to transmit disease, including blacklegged ticks (*Ixodes scapularis* and *Ixodes pacificus*), which are the primary vector for Lyme disease and Anaplasmosis.

Lyme Disease.--The Committee is concerned by reports that cases of Lyme disease are under-reported. Therefore, the Committee urges CDC to re-evaluate surveillance criteria used to track cases of the disease and continue to assist States to more accurately evaluate and assess the prevalence and incidence of the disease. The Committee directs CDC to re-evaluate its surveillance practices in states outside of the regions where Lyme disease is common.

The Committee continues to be concerned about the misuse of the Lyme disease surveillance case definition. While CDC states that the case definition was developed for national reporting and is not appropriate for clinical diagnosis, the definition is reportedly misused as a standard of care for diagnosis, healthcare reimbursement, medical licensing hearings, and other legal cases. The Committee requests that CDC actively work to correct the misuse of this definition, including issuing alerts to the public and to physicians as well as issuing letters to places that misuse this definition. The Committee requests a written plan of action to address this issue to be submitted to the Committee no later than September 30, 2018.

The Committee encourages CDC to investigate transmission of *Borrelia* by other biological vectors, such as mosquitoes and other species of ticks, and to investigate possible blood-borne, sexual, and congenital transmission of Lyme disease.

The Committee encourages CDC to investigate the prevalence of bacterial, viral, and protozoal infections known to cause comorbid infections with *Borrelia burgdorferi*, complicating both the diagnosis and treatment of patients with Lyme disease. Of particular interest are complications caused by co-infection with *Babesia* and *Bartonella*.

The Committee requests that CDC report on implementation of its Lyme disease program. The report should include:

(1) Details on advancing more sensitive and accurate diagnostic tests capable of distinguishing between active and past infections,
(2) Details on efforts to prevent the misuse of the Lyme disease surveillance case definition,
(3) An analysis of the effectiveness of programs for prevention,
(4) Details on how all funds for Lyme disease were spent for fiscal year 2017, and
(5) Results in achieving Lyme disease-related objectives of the NCEZID Strategic Plan 2012–2017 and plans to address any shortfalls in meeting goals.

National Institutes of Health (NIH)

Lyme Disease.--The Committee directs NIH to intensify research that will increase understanding of bacterial, viral, and protozoal infections known to cause comorbid infections with *Borrelia burgdorferi*, complicating both the diagnosis and treatment of patients with Lyme disease. Of particular interest are complications caused by co-infection with *Babesia* and *Bartonella*.

The Committee encourages NIH to issue requests for grant applications for research to investigate causes of all forms and manifestations of Lyme disease, including neurological Lyme disease, seronegative Lyme disease, and chronic Lyme disease, as well as research to develop diagnostics and treatments for those conditions.

The Committee directs NIH to conduct clinical trials to improve treatment outcomes for patients with all forms of Lyme disease, including neurological Lyme disease, seronegative Lyme disease, and chronic Lyme disease. Of particular interest are trials that investigate combination antimicrobial drug therapy, novel therapeutic compounds, use of devices such as blood filters for diagnostic research and treatment, and treatments for patients with co-infecting microorganisms. The Committee encourages NIH to conduct research on mechanisms of persistent infection, including biofilms and dormant forms of *Borrelia* that are resistant to antibiotic treatment. Of particular interest is pathology-based research via microscopy and DNA imaging to identify bacteria that persist after antibiotic treatment.

The Committee requests that NIH report on its Lyme disease program. The report should include:

(1) A summary of ongoing or upcoming efforts to advance more sensitive and accurate diagnostic tests capable of distinguishing between active and past infection, including an analysis of obstacles hindering adoption of direct detection tests for Lyme disease that are currently available or in the pipeline, and
(2) Details on progress achieving NIH Strategic Plan objectives relevant to Lyme disease as well as plans to address any shortfalls in meeting goals.

I believe that the proposed directives herein will achieve improved healthcare outcomes while reducing the economic burden of tick-borne diseases on our economy. The resulting information from proposed actions will help Congress to better quantify and understand healthcare impacts and result in healthcare funding appropriations that reflect more accurately the economic and social burden of tick-borne illness.

Sincerely,

JOHN J. FASO
Member of Congress